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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,489	08/27/2003	Masaki Baba	011552A	4119
23850	7590	03/31/2005		
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EXAMINER MCCLENDON, SANZA L				
ART UNIT			PAPER NUMBER	
1711				

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

Application No.

10/648,489

Applicant(s)

BABA ET AL.

Examiner

Sanza L. McClendon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5 and 7-9 is/are rejected.
- 7) ☐ Claim(s) 4 and 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/926,560.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Response to Amendment***

1. In response to the Amendment received on December 20, 2004, the examiner has carefully considered the amendments.

### ***Terminal Disclaimer***

2. The terminal disclaimer filed on December 20, 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent 6,638,991 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Response to Arguments***

3. Applicant's arguments, see Response, filed December 20, 2004, with respect to the rejection(s) of claim(s) 1-9 under the judicially created doctrine of obviousness-type double patenting have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Yokayama et al (5,346,946).

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 1 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. In claim 1 it is unclear how many carbon atoms are in the alkylene glycol group on line 6 and line 7 on page 65, in line 5 on page 66, in line 16 on page 66, and in line 24 on page 66. Or is applicant intending to claim alkylene glycol groups with unlimited carbon atoms? It is unclear on line 25 on page 65 how many carbon atoms are in the alkyl group substituted with fluorine or phenyl groups.

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7. In claim 1, it is unclear if applicant is intending to claim (E-1) to comprise an acrylate/methacrylate monomer as one of the choices or can E-1 be a diacrylate or a dimethacrylate, in addition to vinyl/methacrylate and allyl/methacrylate type compounds.

8. In the claim 1 the applicant(s) have employed or used improper Markush language, i.e., selected from, in defining the

Markush grouping for the definitions of the diisocyanates in line 11 page 65, definition of S1 and S2 in line 17 page 65, the definition of the diisocyanates line 6 and line 21 page 66, and the definition of E-1 line 8 page 67; and have used the term "and" to link the last two members or only two members of the Markush grouping. The applicants should have used the term "or" instead. The conjunction or term "and" is used when proper Markush language is employed, i.e., "selected from the group consisting of". See M.P.E.P. 2173.05(h).

9. Claim 5 recites the limitations " $\alpha$ ,  $\beta$ ,  $\gamma$ ,  $\delta$ " in lines 5-12. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not have these terms and definitions.

***Claim Rejections - 35 USC § 102/ 35 USC § 103***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-3 and 7-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yokayama et al (5,346,946).

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Yokoyama et al teaches ocular lens materials. Said material comprises a copolymer prepared by heating a monomer mixture or irradiating a monomer mixture with UV or g-rays. Polymerizing by heating comprises heating the monomer mixture in the presence of a free radical initiator from temperatures ranging from room temperature up to 120°C with a time of up to 2 hours, per example 1. Said material can be shaped by polymerizing in a mold or vessel and then processed by cutting—see column 2, lines 44-56. Said copolymer comprises (A) a polysiloxane macromonomer having polymerizable groups bonded via one or more urethane bonds to the siloxanes chain, (B) an alkyl acrylamide, such as N, N'-dimethylacrylamide, (C) a silicon-containing monomer in amounts from at least 10% up to 75%, preferably 60%, such as a silicon-containing alkyl acrylate, such as those found in columns 5-6, (D) a linear, branched or cyclic alkyl (meth) acrylate in amounts up to 60% by weight, (E) a hydrophilic monomer in amounts up to 50% by weight, (F) a fluorine-containing monomer up to preferably 20% by weight, and (G) a crosslinking agent, which can be used singly or in combinations in amounts from 0.1 to 10 parts by weight. Said macromonomer formula can be found in column 2, line 1. This appears to anticipate applicant's macromonomer formula, when n is zero and K is between 1 and 50 and K + L is between 1 and 50. Said hydrophilic monomer (E) can be selected from the group found in column 8, lines 1-15, wherein N-vinylpyrrolidone can be selected. The examiner contends that the alkyl acrylamide (B) and the hydrophilic monomer (E) reads on applicant's hydrophilic monomer mixture (C). Said crosslinking agents can be selected from the group list in column 8, line 68 through column 9, lines 1-22, wherein diethylene glycol di (meth) acrylate and allyl (meth) acrylate are taught. Although Yokoyama et al does not teach adding a crosslinking agent mixture, Yokoyama et al teaches said crosslinking monomers can be used singly or in combinations. Therefore, in the alternative, it would have been obvious for a skilled artisan to add a combination of crosslinking agents. The motivation would have been to impart improved mechanical strength and durability to the resulting ocular lens material as a matter of design choice in the absence of arguments to the contrary. Per example 6, Yokoyama et al teaches a weight ratio of polysiloxane monomer (A) and silicon-containing alkyl (meth) acrylate (C) to the hydrophilic monomers (B + E) is approximately 67:33.5, the ratio of (A) to (B) is 49:50, and the weight ratio of hydrophilic monomer, which can be vinylpyrrolidone to (B) the alkyl acrylamide is 98 to 0.1, all of which are within applicant's ratio ranges found in claim 1.

The inventions of claims 1-3 and 7-9 are anticipated by, or in the alternative, read in the reference.

***Allowable Subject Matter***

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13. Claims 4 and 6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to teach an ocular lens material comprising the copolymer of claim 1 wherein said copolymer is polymerized by irradiating said monomer mixture with ultraviolet rays having a wavelength of 365 nm in illuminance of 0.5 to 20 mW/cm<sup>2</sup> for 1 to 80 min and the monomer mixture also comprises the weight ratios found in claim 4.

### ***Conclusion***

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patents 5,965,631; 5,849,811; 5,789,461; 5,776,999; and 5,760,100 to Nicolson et al teaches extended wear ophthalmic lens comprising a siloxanes macromonomer, which comprises polymerizable bond to a siloxanes main chain through urethane bonds.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sanza L. McClendon whose telephone number is (571) 272-1074. The examiner can normally be reached on Monday through Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1700.

 3/29/05

Sanza L. McClendon

Examiner

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SMc

March 29, 2005